UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,046	09/09/2005	Harald Schlebusch	14836-46758	8798

24728 7590 03/13/2007
MORRIS MANNING MARTIN LLP
3343 PEACHTREE ROAD, NE
1600 ATLANTA FINANCIAL CENTER
ATLANTA, GA 30326

EXAMINER	
AEDER, SEAN E	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,046	SCHLEBUSCH ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13 and 14* is/are rejected.

7)☒ Claim(s) *1 and 2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 1/3/07 in response to the Office Action of 10/3/06 are acknowledged and have been entered.

Claims 13-14 have been added by Applicant.

Claims 1-14 are pending.

Claims 1-11 have been amended by Applicant.

Claim 12 had been withdrawn for being drawn to an unelected invention.

The text of those sections of Title 35 U.S.C. code not included in this Office Action can be found in a prior Office Action.

The following Office Action contains NEW GROUNDS of rejections based on new considerations.

Objections Withdrawn

The objection to claims 7-11 is withdrawn in view of amendments.

Rejections Withdrawn

The rejection of claims 1 and 3-5 under 35 U.S.C. 101 has been withdrawn.

The *second* rejection of claims 1-6 under 35 U.S.C. first paragraph, for failing to comply with the enablement requirement, has been withdrawn.

Response to Arguments

35 USC § 112, first paragraph (First Enablement Rejection of 10/3/06)

The first rejection of claims 2-6 under 35 U.S.C. 112 first paragraph, for failing to comply with the enablement requirement, is maintained for the reasons stated in the Office Action of 10/3/06 and for the reasons set-forth below.

The Office action of 10/3/06 contains the following text:

"The invention appears to employ novel biological materials, specifically monoclonal anti-idiotypic antibody ACA125 produced by the hybridoma 3D5 (DSM ACC2120). Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of

compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit will be made (see 37 C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. 2400 in general, and specifically to 2411.05, as well as 37 C.F.R. 1.809(d), wherein it is set forth that the "specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209"

In response to the Office Action of 10/3/06, Applicant states: "...that the deposit of the specific biological materials DSM ACC2120 was already effected on March 3, 1993 under the Budapest treaty. Thus, the DSM ACC2120 was irrevocably and without restriction or condition released to the public". Applicant further provided a deposit receipt for DSM ACC2120.

The response to the Office Action of 10/3/06 has been carefully considered, but is not deemed persuasive. In regards to the argument that the deposit of the specific biological materials DSM ACC2120 was already effected on March 3, 1993 under the Budapest treaty and that such deposit would irrevocably and without restriction or condition release DSM ACC2120 to the public, a deposit of biological materials under the Budapest treaty does not necessarily result in the irrevocable and without restriction release of said biological materials. As noted in the Office Action of 10/3/06, if the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. Thus, it is suggested Applicant submit an affidavit, declaration, or a statement by the attorney of record over his or her signature and registration number stating that said deposited biological materials will be

irrevocably and without restriction or condition released to the public upon the issuance of a patent.

New Objections

Claims 1 and 2 are objected to for reciting antibodies which "react" with other antibodies or antigens. One of skill in the art would recognize that antibodies do not "react" with antibodies and/or antigens; rather, antibodies "specifically bind" antigens and/or antibodies. It is suspected Applicant intended to claim antibodies that "specifically bind" rather than "react" with antibodies and/or antigens. Proper correction is required.

New Rejections Necessitated by New Considerations

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al (US Patent 5,858,361; 1/12/99).

Claim 1 is drawn to an isolated anti-anti-idiotypic antibody characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with

this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. Claim 2 is drawn to the isolated anti-anti-idiotypic antibody as claimed in claim 1, characterized in that it reacts with the monoclonal antibody ACA125 produced by hybridoma 3D5, which is deposited under DSM ACC2120. Claim 3 is drawn to the isolated anti-anti-idiotypic antibody as claimed in claim 1 or claim 2, characterized in that it is produced as a result of a polyclonal immune response by vaccination with an anti-idiotypic antibody which represents an internal image of the antigen CA125. Claim 4 is drawn to the isolated anti-anti-idiotypic antibody as claimed in claim 1 in that it is produced recombinantly. Claim 9 is drawn to a pharmaceutical composition comprising an anti-anti-idiotypic antibody as claimed in claim 1. Claim 11 is drawn to the pharmaceutical composition as claimed in claim 9 for the treatment and/or prophylaxis of CA1125-expressing tumors.

Wagner et al teaches a pharmaceutical composition comprising an isolated anti-anti-idiotypic antibody created by a polyclonal immune response by vaccination with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen –binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells (column 8, in particular). Further, Wagner et al teaches that said anti-anti-idiotypic antibody was

produced using recombinant techniques (see Example 2, in particular) It is noted that claim 11 does not further limit the claim from which it depends; rather, claim 11 merely recites an intended use of the product of claim 9. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as a product which is intended to be used to treat tumor growth are not given patentable weight and are not limitations to the claims. Further, although Wagner et al does not explicitly state that the anti-anti-idiotypic antibodies bind CA125 antigen, the isolated anti-anti-idiotypic antibody taught by Wagner is made by the same process disclosed in the instant application (see page 3, in particular) and appears to be the same as the claimed product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed product is different from that taught by the prior art and to establish patentable differences. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2nd 1992 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 102

Claims 1, 3, 4, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultes et al (Cancer Immuno Immunother, 3/98, 46:201-212).

Claims 1, 3, 4, 9, and 11 are described above.

Schultes et al teaches a pharmaceutical composition comprising an isolated anti-anti-idiotypic antibody produced as a result of a polyclonal immune response by vaccination with an anti-idiotypic antibody which represents an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells (see abstract and pages 202 and 206-208, in particular). Schultes et al further teaches that said anti-anti-idiotypic antibody was produced using recombinant techniques (see left column of page 202, in particular). It is noted that claim 11 does not further limit the claim from which it depends; rather, claim 11 merely recites an intended use of the product of claim 9. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as a product which is intended to be used to treat tumor growth are not given patentable weight and are not limitations to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (US Patent 5,858,361; 1/12/99) in view of Bhattacharya-Chatterjee et al (The Journal of Immunology, 10/15/90).

Claims 1-4, 9, and 11 are described above. Claim 5 is drawn to the isolated anti-anti-idiotypic antibody as claimed in claim 1 or 2, characterized in that it is produced by hybridoma cells as a monoclonal antibody.

Wagner et al teaches as described above. Wagner et al does not teach an isolated anti-anti-idiotypic antibody produced by hybridoma cells as a monoclonal

antibody which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen – binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. However, these deficiencies are made up in the teachings of Bhattacharya-Chatterjee et al.

Bhattacharya-Chatterjee et al teaches an anti-anti-idiotypic antibody for CEA that is produced by hybridoma cells as a monoclonal antibody (left column of page 2762, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to use hybridoma cells to produce a monoclonal anti-anti-idiotypic antibody, as taught by Bhattacharya-Chatterjee et al, which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen –binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by Wagner et al, because Wagner et al teach that said anti-anti-idiotypic antibody is to be used for therapeutic purposes (see column 8, in particular) and one of skill in the art would recognize that monoclonal antibodies are preferable to polyclonal antibodies for therapeutic purposes because use of

hybridoma cells to produce monoclonal antibodies allows one to generate a more uniform product that can be indefinitely produced, whereas polyclonal antibodies result in great variation with varying therapeutic efficacy. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using hybridoma cells to produce an anti-anti-idiotypic antibody, as taught by Bhattacharya-Chatterjee et al, which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen –binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells because Bhattacharya-Chatterjee et al teaches an anti-anti-idiotypic antibody for CEA that is produced by hybridoma cells as a monoclonal antibody (left column of page 2762, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 3-5, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultes et al (Cancer Immuno Immunother, 3/98, 46:201-212) in view of Bhattacharya-Chatterjee et al (The Journal of Immunology, 10/15/90).

Claims 1, 3-5, 9, and 11 are described above.

The teachings of Schultes et al are described above.

Schultes et al does not specifically teach a pharmaceutical composition comprising an isolated anti-anti-idiotypic antibody produced by hybridoma cells as a monoclonal antibody which represents an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. However, these deficiencies are made up in the teachings of Bhattacharya-Chatterjee et al.

The teachings of Bhattacharya-Chatterjee et al are described above.

One of ordinary skill in the art at the time the invention was made would have been motivated to use hybridoma cells, as taught by Bhattacharya-Chatterjee et al, to produce anti-anti-idiotypic monoclonal antibodies which represent an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells because Schultes et al teaches using anti-anti-idiotypic antibodies for therapeutic purposes (page 208 and Figure 5a, in particular) and one of skill in the art would recognize that monoclonal antibodies are preferable to polyclonal antibodies for therapeutic purposes because use of hybridoma cells to produce monoclonal antibodies allows one to generate a more uniform product that can be indefinitely produced, whereas polyclonal

antibodies result in great variation with varying therapeutic efficacy. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using hybridoma cells to produce anti-anti-idiotypic antibodies which represent an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells because Bhattacharya-Chatterjee et al teaches an anti-anti-idiotypic antibody for CEA that is produced by hybridoma cells as a monoclonal antibody (left column of page 2762, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1-6, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (US Patent 5,858,361; 1/12/99) in view of Bhattacharya-Chatterjee et al (The Journal of Immunology, 10/15/90) and Gigliotti et al (J Clin Invest, 12/82, 70:1306-1309).

Claims 1-5, 9, and 11 are described above. Claim 6 is drawn to a human hybridoma cell line which produces the monoclonal ant-anti-idiotypic antibody of claim 5.

The combined teachings of Wagner et al and Bhattacharya-Chatterjee et al are described above.

The combined teachings of Wagner et al and Bhattacharya-Chatterjee et al does not specifically teach an anti-anti-idiotypic monoclonal antibody produced by human hybridoma cells which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen –binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. However, these deficiencies are made up in the teachings of Gigliotti et al.

Gigliotti et al teaches therapeutic monoclonal antibodies generated by human hybridoma cells (page 306-307).

One of ordinary skill in the art at the time the invention was made would have been motivated to create an anti-anti-idiotypic monoclonal antibody produced by human hybridoma cells, as taught by Gigliotti et al, which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen –binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by the combined teachings of Wagner et al

and Bhattacharya-Chatterjee et al, because Gigliotti et al teaches that human hybridoma cells, rather than murine hybridoma cells, are required to avoid sensitization to foreign proteins with in vivo therapeutics (see left column of page 1306, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for creating an anti-anti-idiotypic monoclonal antibody produced by human hybridoma cells, as taught by Gigliotti et al, which represents an internal image of the antigen CA125 characterized in that it (i) binds with the anti-idiotypic monoclonal antibody ACA125 produced by hybridoma 3D5 which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and binds with tissues expressing this antigen –binding which can be inhibited by anti-CA125 antibodies, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by the combined teachings of Wagner et al and Bhattacharya-Chatterjee et al, because Gigliotti et al teaches methods of making therapeutic monoclonal antibodies generated by human hybridoma cells (page 306-307). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultes et al (Cancer Immuno Immunother, 3/98, 46:201-212) in view of

Bhattacharya-Chatterjee et al (The Journal of Immunology, 10/15/90) and Gigliotti et al (J Clin Invest, 12/82, 70:1306-1309).

Claims 1, 3-6, 9, and 11 are described above.

The combined teachings of Schultes et al and Bhattacharya-Chatterjee et al are described above.

The combined teachings of Schultes et al and Bhattacharya-Chatterjee et al does not specifically teach anti-anti-idiotypic monoclonal antibodies, produced by human hybridoma cells, which represent an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. However, these deficiencies are made up in the teachings of Gigliotti et al.

The teachings of Gigliotti et al are described above.

One of ordinary skill in the art at the time the invention was made would have been motivated to use human hybridoma cells, as taught by Gigliottie et al, to produce anti-anti-idiotypic monoclonal antibodies which represent an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by the combined teachings of Schultes et al and Bhattacharya-Chatterjee et al, because

Gigliotti et al teaches that human hybridoma cells, rather than murine hybridoma cells, are required to avoid sensitization to foreign proteins with in vivo therapeutics (see left column of page 1306, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using human hybridoma cells, as taught by Gigliottie et al, to produce anti-anti-idiotypic monoclonal antibodies which represent an internal image of the antigen CA125 characterized in that it (i) specifically binds an anti-idiotypic antibody which represents an internal image of the antigen CA125, (ii) is specific for the tumour-associated antigen CA125 and specifically binds CA125, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by the combined teachings of Schultes et al and Bhattacharya-Chatterjee et al because Gigliotti et al teaches methods of making therapeutic monoclonal antibodies generated by human hybridoma cells (page 306-307). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 3, 4, 7-9, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being unpatentable by Schultes et al (Cancer Immuno Immunother, 3/98, 46:201-212) in view of Carlson et al (PNAS, 11/77, 74(11):5126-5130).

Claims 1, 3, 4, 9, and 11 are described above. Claim 7 is drawn to a fragment of an anti-anti-idiotypic antibody as claimed in claim 1, characterized in that it has the

binding specificity of an anti-anti-idiotypic antibody. Claim 8 is drawn to the fragment as claimed in claim 7, characterized in that it comprises a Fab or $F(ab)_2$ fragment of the anti-anti-idiotypic antibody optionally coupled to a human Fc part. Claim 13 is drawn to a pharmaceutical composition comprising a fragment as claimed in claim 7. Claim 14 is drawn to a pharmaceutical composition comprising a fragment as claimed in claim 8.

The teachings of Schultes et al are described above.

Schultes et al does not specifically teach a pharmaceutical composition comprising a Fab or $F(ab)_2$ fragment of an anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. However, these deficiencies are made up in the teachings of Carlson et al.

Carlson et al teaches pharmaceutical compositions comprising antigen-binding Fab and Fab_2 fragments of antibodies (right column of page 41, in particular). Carlson et al further teaches that antigen-binding Fab and Fab_2 fragments were able to access to tumors better than the antibodies from which said fragments were derived (right column of page 49, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce a pharmaceutical composition comprising a Fab or $F(ab)_2$ fragment, as taught by Carlson et al, of the anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the

antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by Schultes et al, because Schultes et al teaches that said anti-anti-idiotypic antibody is to treat ovarian tumors and Carlson et al teaches antigen-binding Fab and Fab_2 fragments access tumors better than the antibodies from which they were derived (right column of page 49, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing a pharmaceutical composition comprising a Fab or $F(ab)_2$ fragment, as taught by Carlson et al, of the anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by Schultes et al, because Carlson et al teaches Fab or $F(ab)_2$ fragments generated by parent antibodies (page 41, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 3, 4, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultes et al (Cancer Immuno Immunother, 3/98, 46:201-212) in view of Urbain et al (PNAS, 11/77, 74(11):5126-5130).

Claims 1, 3, 4, 9, and 11 are discussed above. Claim 10 is drawn to a pharmaceutical composition comprising an anti-anti-idiotypic antibody as claimed in claim 1 that additionally contains common pharmaceutical carriers and adjuvants.

The teachings of Schultes et al are described above. Schultes et al further teaches anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells in pharmaceutical compositions comprising the common pharmaceutical carriers PBS 10.M glycine/HCL, pH 3.0.

Schultes et al does not specifically teach a pharmaceutical composition comprising common pharmaceutical carriers and adjuvants and an anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells. However, these deficiencies are made up in the teachings of Urbain et al.

Urbain et al teaches methods of using pharmaceutical compositions comprising pharmaceutical carriers, adjuvants, and Ab1 antibodies to produce Ab2 antibodies (right column of page 5126, in particular).

One of skill in the art would recognize that the anti-anti-idiotypic antibodies of the claimed invention are indistinguishable from Ab1 antibodies from which they were originally derived.

One of ordinary skill in the art at the time the invention was made would have been motivated to produce a pharmaceutical composition comprising common pharmaceutical carriers and adjuvants, as taught by Urbain et al, and an anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by Schultes et al, because said anti-anti-idiotypic antibody is indistinguishable from the Ab1 antibody from which it was originally derived and one of skill in the art would recognize that a pharmaceutical composition comprising said anti-anti-idiotypic antibody, a carrier, and an adjuvant, would enhance an immune response to ultimately create larger quantities of the therapeutic anti-anti-idiotypic antibody taught by Schultes et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing a pharmaceutical composition comprising common pharmaceutical carriers and adjuvants, as taught by Urbain et al, and an anti-anti-idiotypic antibody, characterized in that it (i) reacts with an anti-idiotypic antibody which represents an internal image of the antigen of CA125, (ii) is specific for the tumour-associated antigen CA125 and reacts with this antigen, and (iii) mediates an antibody-dependent cellular cytotoxicity against CA125-expressing tumour cells, as taught by

Schultes et al because said anti-anti-idiotypic antibody is indistinguishable from the Ab1 antibody from which it was originally derived and Urbain et al teaches pharmaceutical compositions comprising carriers, adjuvants, and Ab1 antibodies right column of page 5126, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600